K062552

510(k) Summary

OCT - 6 2006

Optovue, Incorporated
RTVue

This 510(k) summary for the RTVue is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

Manufacturer:

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Device Information

Classification: Class II

Trade Name: RTVue

Common Name: Optical Coherence Tomography (OCT)

Classification Name: Ophthalmoscope, a-c powered (21 CFR§ 886.1570)

Predicate Device

Humphrey® OCT3 (K012727)

Intended Use

The RTVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal diseases.

Device Description

RTVue, based on the same Optical Coherence Tomography (OCT) technology that is using in the predicate device Humphrey® OCT3 (K012727), is a non-invasive diagnostic device for viewing the ocular tissue structure with micrometer range resolution. A brochure of the OCT3 system is in appendices [1]

The RTVue, like its predicate device Humphrey® OCT3 (K012727), is a computer controlled ophthalmic imaging system. The device scan a beam into patient's eye and use a low coherence interferometer to measure the reflectivity of the retinal tissue. The cross sectional retinal tissue structure is composed of sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The device is mounted on a motorized patient table. The patient will rest their head on the forehead and chin rest. Operator uses joystick to align the device to patient's eye. The computer has a graphic user interface for acquire and analysis image.

The RTVue has improvements in image acquisition speed and image resolution over its predecessor. RTVue uses non-mechanic moving part in the depth scan, a branch of OCT technology called Fourier Domain-OCT, so the scan speed improves about 65 times faster than the mechanical limited scan speed in previous devices. A detail description of the technology improvement from predicate device is published in Optics Express, May 2004 by Leitgeb et. al. Appendices [2, a].

The RTVue also uses the same light source SLD (super luminescent diode) as in its predicate device but with broader spectral bandwidth. The broad spectral bandwidth provides higher image resolution than a narrow one based on the Optical Coherence Tomography principle. A paper describes the technology improvement from predicate device is published in Optics Express, May 2004 by Ko et. al. Appendices [2,b] and in American Journal of Ophthalmology, September 2004 by Wojtkowski et. al. Appendices [2. c]. Ocular pathologies imaged with the Fourier domain OCT and ultrahigh resolution light source also has been published in Investigative Ophthalmolgy & Visual Science , September 2005 by Schmidt-Erfurtb et. al. Appendices [2,d] and in American Academy of Ophthalmology, October 2005 by Wojtkowski, et. al Appendices [2,e].

Safety

The power of the scan beam enter into patient's pupil is at same level as predicate device. The detail safety analysis Appendices [3] is completed by an international recognized expert in the field of optical radiation hazards and safety Dr. Dave Sliney. The conclusion of the analysis is "The Optovue Retinal OCT system emits near-infrared radiation from an SLD that is below all of the applicable exposure limits-including the guidelines for ophthalmic instrument exposure"

Effectiveness

The predicate device has been routinely used in clinic. Numerous clinic paper and data has been published over last 10 years. The comparison between high resolution and regular resolution OCT image produced by predicate device shows same and in some cases better clinic diagnosis can be produced by the higher resolution device. A clinic evaluation of high resolution OCT image in diagnosis retinal diseases has been published in SPIE Proceeding vol. 4956, 2003 by Ko et. al. Appendices [2,f]. The summary of the paper is "Intraretinal architectural morphology associated with macular diseases such as macular edema, epiretinal membranes, and macular holes can be visualized

with unprecedented resolution. Ultrahigh resolution ophthalmic OCT promises to improve the early diagnosis of retinal diseases as well as enable monitoring of disease progression and the efficacy of therapeutic intervention.".

Substantial Equivalence

The RTVue is substantially equivalent to the predicate device identified previously. The RTVue is substantially equivalent to the predicate device with regard to intended use, operating principle, function, material, and energy source. The only difference from the predicate device is that the RTVue has an increased scan rate and high image resolution. A comparison of ultrahigh resolution and Standard-resolution OCT (the predicate device) paper publish by Tony Ko et., appendices [2, al in Journal of Ophthalmology 2005 , concludes that "Ultrahigh-resolution OCT and standard resolution OCT exhibited comparable performance in differentiating thicker retinal layers, such as the retina nerve fiber, inner and outer plexiform, and inner and outer nuclear."

Performance Data

(a) Non-clinic tests:

The RTVue has had accuracy tests, optical emission safety analysis, electrical safety, electromagnetic compatibility test, and software validation tests.

(b)Clinic tests:

Not Required

Conclusion

As described in this 510(k) Summary, all testing and analysis were conducted on the RTVue to ensure that the device is safe and effective for its intended use when used in accordance with its instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2007

Optovue, Inc.
c/o Mr. Tamas Borsai
TUV Rheinland of North America
12 Commerce Road
Newton, CT 06470

Re: K062552
Trade/Device Name: RTVue
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: September 19, 2006
Received: September 21, 2006

Dear Mr. Borsai:

This letter updates our substantially equivalent letter of January 26, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your

device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Gwenette T. Burns PhD

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k062552

Device Name:_RTVue

Indications For Use:

The RTVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal diseases.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R. Butterfield

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K062552

Rev 09/15/06